Army Regulation 40-70 NAVSUPINST 4355.6A MCO 10110.44A

**Medical Services** 

Department of Defense Veterinary/Medical Laboratory Food Safety and Quality Assurance Program

Headquarters
Departments of the Army, and the U.S.
Marine Corps
Washington, DC
1 February 1995

**Unclassified** 

# SUMMARY of CHANGE

AR 40-70/NAVSUPINST 4355.6A/MCO 10110.44A Department of Defense Veterinary/Medical Laboratory Food Safety and Quality Assurance Program

#### This revision--

- o Updates and consolidates information previously published as AR 40-70/NAVSUPINST 4355.6/AFR 161-46/MCO 10110.44, chapter 4, AR 40-657/NAVSUPINST 4355.4F/MCO P10110.31G, and AR 40-661/NAVMEDINST 6240.2/AFR 161-72/MCO 10110.41A/DLAR 4155.35.
- o Changes the title of the regulation to reflect current Veterinary/Medical Service responsibilities.
- o Prescribes policies and laboratory functions of the veterinary laboratory service (paras 1-4c, 1-4d, and app B).
- o Associates quality assurance visits and origin and destination sampling with a program for monitoring the wholesomeness and quality of pre-packaged and/or processed, ready-to-eat potentially hazardous foods that are not already under constant U.S. Government inspection (chaps 2, 3, and 4).
- o Prescribes requirements and standards for assuring food safety and quality assurance for potentially hazardous foods (chap 4).
- o Establishes guidelines for laboratory and/or surveillance screening of potentially hazardous foods (chap 4).
- o Directs the use of DD Form 1232 (Quality Assurance Representative's Correspondence) as the reporting form for notification of noncomplying products; deletes the use of DD Form 2386 for this purpose (para 4-3c).
- o Provides for additional sampling for Government testing during reinstatement (para 4-4).
- o Establishes guidelines for microbiological monitoring of ground meat processing, and soft serve ice (cream) milk and yogurt processing at the retail/user level (chap 5).
- o Revises and prescribes the use of DD Form 2385 (Microbiological Quality History Record) to meet the needs of contracting officials and inspection personnel (app C).
- o Adds the management control evaluation process to evaluate key management controls (app D).

Headquarters
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Effective 1 March 1995

#### **Medical Services**

## Department of Defense Veterinary/Medical Laboratory Food Safety and Quality Assurance Program

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**History.** This UPDATE printing publishes a revision of this publication. This publication has been reorganized to make it compatible with the Army electronic publishing database. No content has been changed.

**Summary.** This consolidated regulation on Food Safety Evaluation Programs prescribes: policies and functions of the veterinary laboratory service; and specialized requirements and microbiological standards for assuring food safety and quality assurance for potentially hazardous foods. It incorporates food safety evaluation and quality assurance evaluation of fresh and cultured dairy products, frozen desserts, soft serve ice (cream) milk and yogurt, salad–type convenience foods, coarse ground and/or chopped beef products, ground meat and poultry products, and pre–packaged and/or processed, ready–to–eat potentially hazardous foods.

Applicability. This regulation applies to the Active and Reserve Components of the Army, the Navy, and the Marine Corps, and inspections made at the request of the U.S. Coast Guard under the Interservice Support Agreement. It applies to the laboratory services and to the inspection of potentially hazardous foods purchased locally or centrally for the Armed Forces with appropriated or non–appropriated funds. This regulation applies to the inspection of civilian food establishments serving as sources of these products and inspections performed for other

U.S. Federal agency programs when covered by a written support agreement and cited in the contract (such as the Veterans Administration, Job Corps, and Indian Schools). This publication is applicable during mobilization.

Proponent and exception authority. The Office of The Surgeon General is the proponent of this regulation. The proponent has the authority to approve exceptions to this regulation that are consistent with controlling law and regulation. Proponents may delegate the approval authority, in writing, to a division chief under their supervision within the proponent agency who holds the grade of colonel or the civilian equivalent.

# **Army management control process.** This regulation contains management control provisions in accordance with AR 11–2 and

provisions in accordance with AR 11–2 and contains checklists for conducting management control reviews.

**Supplementation.** Users of this regulation will not supplement this regulation or establish and use command and local forms without prior approval from HQDA (DASG-VCP), 5109 Leesburg Pike, Falls Church, VA 22041–3258.

**Interim changes.** Interim changes to this regulation are not official unless they are authenticated by the Administrative Assistant to the Secretary of the Army. Users will destroy

interim changes on their expiration dates unless sooner superseded or rescinded.

**Suggested Improvements.** Users may send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) or a memo directly to HQDA (DASG-VCP), 5109 Leesburg Pike, Falls Church, VA 22041–3258.

**Distribution.** *Army:* Distribution of this publication is made in accordance with the requirements of DA Form 12–09–E, block number 3448, intended for command level B for Active Army; command level D for the Army National Guard; and command level D for the U.S. Army Reserve.

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<sup>\*</sup>This regulation supersedes AR 40–70/NAVSUPINST 4355.6/AFR 161–46/MCO 10110.44, 15 April 1986; chapter 4, AR 40–657/NAVSUPINST 4355.4F/MCO P10110. 31G, 19 July 1988; AR40–661/NAVMEDINST 6240.2/AFR 161–72/MCO 10110.41A/DLAR 4155.35, 1 September 1986. It rescinds DD Form 2386, June 1983.

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## Chapter 1 Introduction

#### 1-1. Purpose

- a. This regulation—
- (1) Outlines concepts and policies and prescribes procedures and techniques for food safety and quality assurance (QA) programs essential to protecting military personnel from foodborne illness.
- (2) Describes the concepts and design for a food safety (risk reduction) program targeted at potentially hazardous foods (PHFs) not inspected in accordance with other U.S. Federal or State agency programs within the continental United States (CONUS).
- b. The U.S. Army Veterinary Service and the U.S. Army Veterinary Laboratory (USAVL) Service will use existing Department of Defense (DOD) inspection resources to minimize the cost. The U.S. Army Veterinary Service, as the DOD Executive Agent for Veterinary Services, will administer the food safety and QA programs to assure standardization and uniformity of inspection and to meet the health concerns of the individual Services and departments (DOD Directive 6015.5). These programs will include quality assurance visits (QAVs) in conjunction with an origin and/or destination product monitoring and surveillance program at establishments not under direct in-establishment inspection by U.S. Federal authorities (that is, Food and Drug Administration, (FDA) U.S. Department of Agriculture (USDA), U.S. Department of Commerce, (USDC)) or U.S. Federally recognized State authorities. Programs initiated under the authority of this regulation are to supplement, not duplicate, existing U.S. Federal and State programs in CONUS.
- c. Contracting agencies will incorporate this regulation's provisions into all subsistence contracts.

#### 1-2. References

Required and related publications and prescribed and referenced forms are listed in appendix A.

#### 1-3. Explanation of abbreviations and terms

Abbreviations and special terms used in this regulation are explained in the glossary.

#### 1-4. Responsibilities

- a. The Surgeon General (TSG), Department of the Army (DA), after coordinating with TSGs of the other Services, or their designated representatives, will—
- (1) Prescribe standards for product wholesomeness and establishment sanitation.
- (2) Develop uniform, efficient procedures to verify contractor compliance with contractual food safety requirements and establishment sanitation standards.
- (3) If requested to do so, resolve interservice coordination problems.
- b. The Staff Veterinarian at each Major Army Command (MACOM) and the Naval Supply Systems Command Staff Veterinarian will—
- (1) Implement the food safety and QA programs contained in this regulation.
- (2) Appoint an appropriate individual to function as the "Food Safety and Quality Assurance Program Authority" (Program Authority).
- (3) Implement and/or coordinate implementation of the food safety and QA programs of other commands and Services with the Chief, DOD Veterinary Laboratory (DODVL) or supporting overseas USAVL (app B).
- (4) Coordinate destination product sampling and QA programs respective to their area of operation (AO).
- (5) Notify applicable personnel of delivery suspension due to an imminent health hazard or failure of the source establishment to maintain acceptable quality control (QC) or required establishment sanitation.
- (6) Assure uniform application of procedures consistent with QA standards of the purchasing agency.

- (7) Coordinate with other military offices and U.S. Federal or State agencies to assure administrative and uniform control throughout their AO.
- c. The Chief, DODVL, Veterinary Services, Brooke Army Medical Center (BAMC) will—
- (1) Be responsible for standardization of veterinary laboratory operations and procedures of the U.S. Army Veterinary Command and MACOM veterinary laboratories. (See app B.)
- (2) Establish microbiological/chemical standards after presentation to and concurrence of TSG, DA.
- (3) Serve as laboratory advisor to the Assistant Surgeon General for Veterinary Services; conduct annual technical inspections and proficiency surveys of the dairy testing facilities used by dairy contractors supplying products for U.S. Forces. In the European Command, the Chief, USAVL–Europe has this responsibility. Additionally, the Chief, USAVL–Europe will inspect U.S. military QA laboratories that perform analysis of fresh dairy foods.
- (4) As a lab Chief, perform the responsibilities listed in paragraph d below.
  - d. Chiefs of USAVLs will—
- (1) Function as the Program Authority unless otherwise directed by the MACOM Veterinarian.
- (2) Administer the food safety and QA programs, as referenced, for each producing establishment within their AO.
- (3) Conduct microbiological, chemical, toxicological, and radiological analysis of subsistence, nonprescription drugs, and cosmetics to assist submitting inspectors to determine whether these items—
  - (a) Are fit for consumption, issue, or resale.
  - (b) Conform with contractual requirements.
  - (4) Inform submitter of results as expeditiously as possible.
- (5) Coordinate destination product sampling and QA programs respective to their AO.
- (6) Notify applicable personnel of delivery suspension due to an imminent health hazard or failure of the source establishment to maintain acceptable QC or required establishment sanitation.
- (7) Coordinate with Veterinary Unit Commanders, prime contractors, subcontractors, contracting officers, destination inspectors, and U.S. State or local health agencies as applicable.
  - (8) Assign inspection units to submit samples (CONUS only).
- (9) Maintain master microbiological quality history records (QHRs) (CONUS only).
- (10) Assign inspection responsibility when origin QAV is requested (CONUS only).
- (11) Collect contracts from DOD and service level procurement agencies within the AO.
- (12) Serve as laboratory technical advisors to MACOM Veterinarians.
- (13) Publish and distribute technical data letters, laboratory standing operating procedures, and laboratory administrative procedures as needed.
- (14) Maintain liaison with various laboratories to obtain and disseminate technical information concerning veterinary issues peculiar to the AO. This includes commercial, Federal, State, city, county, educational institutions, and laboratories of foreign or host countries.
- e. When the MACOM Veterinarian directs, veterinary or medical origin food inspection personnel will—
- (1) Administer the food safety and QA programs, as referenced, for each producing establishment within their AO.
- (2) Coordinate with the Chief, USAVL; Veterinary Unit Commander; prime contractors; subcontractors; contracting officers; destination inspectors; and U.S. State or local health agencies as applicable.
- (3) Notify the MACOM Veterinarian of immediate health threats detected at origin during QAVs.
- f. Veterinary/medical destination food inspection personnel will—
- (1) Assure that products originate from a sanitarily approved source and arrive in a sanitary conveyance at the proper temperature.

- (2) Present QA requirements to contracting agencies and forward local contracts to the Program Authority.
- (3) Submit test samples (selected at time of delivery) per this regulation.
- (4) Provide the Program Authority with information concerning significant installation commander complaints and desires or consumer complaints about problems at the destination.
- (5) Inform the ordering officer when a producer is in a warning status due to unreliable microbiological quality history and/or QC and/or when delivery of a product is suspended.
- (6) Reject products that a contractor delivers when that product has been suspended (and not reinstated); report the nonconformance to the procuring officer or contracting officer and Veterinary Unit Commander as applicable. When required, send written confirmation of rejections to the Program Authority on DD Form 1232 (Quality Assurance Representative's Correspondence).
- (7) Maintain QHR for those vendors whose QHR is NOT maintained by the Program Authority.
  - g. Purchasing and contracting personnel will-
- (1) Cite this regulation in each contractual document for subsistence procurement.
- (2) Award contracts or purchase orders only to suppliers using sanitarily approved food establishments (such as those approved by the Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List), USDA, or the Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement (known as the Directory)) as sources for each item.
- (3) When appropriate and in accordance with applicable procurement regulations, suspend or terminate contracts or purchase orders for contractor failure to comply with the terms of the contract and this regulation.
  - (4) Provide all applicable contracts to the Program Authority.
  - h. Contractors and/or distributors will—
- (1) Comply with the establishment sanitation provisions of AR 40–657/NAVSUPINST 4355.4F/MCO P10110.31G.
- (2) Comply with the applicable provisions of Title 21, Code of Federal Regulations (21 CFR); sections 301–392, Title 21, United States Code (21 USC 301–392) (The Federal Food, Drug, and Cosmetic Act); sections 1451–1461, Title 15, United States Code (15 USC 1451–1461) (Fair Packaging and Labeling Act); the Grade "A" Pasteurized Milk Ordinance (PMO) as amended (MACOM Veterinarians may make authorized exceptions); applicable U.S. State laws and regulations; and this regulation. Failure to do so will result in rejection of deliveries by veterinary or medical personnel and subsequent contract suspension, and/or contract termination.
- (3) Perform or cause to be performed at contractor expense such laboratory tests as necessary to assure compliance with product microbiological requirements as specified in this regulation, the PMO as amended, and contractual documents. They will also provide the results of such tests for review by the responsible origin inspector during normal operating hours. Failure to do so will result in rejection of deliveries by veterinary or medical food inspection personnel and subsequent contract suspension, and/or contract termination.
- (4) Have an establishment's management representative responsible for QC or sanitation accompany the veterinary food inspector during QAV or sanitary inspections.
- (5) Take immediate corrective action when internal evaluation so indicates or when advised of Government test or examination failures.
- (6) Provide, in writing, code dates and marking code information to identify the date of pasteurization, production or packaging, as applicable and required by the contractual documents.
- (7) Provide source of manufacture information to the applicable origin and destination inspectors prior to or concurrent with the first delivery and when there is any change in this information. Additionally, provide a copy of the code/marking information to the applicable purchasing or contracting activity.

#### 1-5. Inspection guidance

Additional inspection guidance is in the following references:

- a. The terms of the purchase instrument.
- b. Grade "A" PMO.
- c. Military Standard (MIL-STD) 668.
- d. MIL-STD 1155.
- e. MIL-STD 1162.
- f. MIL-STD 1481.
- g. MIL-STD 1482.
- h. Federal Acquisition Regulation (FAR).
- i. DOD FAR Supplement.
- j. 21 CFR.
- k. 15 USC.

## Chapter 2 Concepts and Policies

#### 2-1. Concepts

The basic concept of these programs is to obtain an acceptable degree of product wholesomeness and quality by relying on a contractor's QC history with a minimum expenditure of U.S. Government resources. This regulation provides the minimum acceptable contractor's performance and the frequencies of U.S. Government inspection and testing procedures.

#### 2-2. Policies

The following policies form the basis for the procedures specified in this regulation.

- a. Objective. These programs—
- (1) Supplement wholesomeness and QA applied to PHF where U.S. Government inspection agencies (Federal or State) either have no like sampling programs, or are not in the establishment during all operational hours.
- (2) Provide uniform standards to all contractors supplying fresh and cultured dairy products (including IMS List establishments), frozen desserts, soft serve ice cream/milk and yogurt, sandwiches and spreads, salad type convenience foods, and other processed/pre-packaged and ready-to-eat (RTE) foods to the military Services.
  - b. Samples to monitor and verify vendor compliance.
- (1) The USAVL managed destination sample monitoring and verification concept is the norm unless the MACOM Veterinarian directs otherwise. The MACOM Veterinarian may designate control and coordination of the program in his/her AO to local military veterinary commanders.
- (2) The origin inspector will perform a QAV when contractors exceed "M" values. Inspectors will select the first verification sample(s) at origin as part of the QAV.
- c. Relationship of PMO to wholesomeness and QA procedures. The origin microbiological and QA procedures follow the general concepts of the PMO. The Program Authority will determine the frequency of testing based on a product's quality history as recorded on the DD Form 2385 (Microbiological Quality History Record). (See app C.)
- d. Keeping quality (KQ) tests. The U.S. Government relies on the contractor for maintaining QC for all items produced. Manufacturers of fresh fluid dairy products are encouraged to perform either the Mosley Keeping Quality (MKQ) or Preliminary Incubation (PI) count (also known as the Virginia Tech Shelf Life Pre–Incubation Test). The U.S. Army Veterinary Service will use the results as guidelines to ensure a quality product with the stated shelf life period.
- e. Use of product test results. Product test results are usually "after consumption" data. Therefore, the responsible inspectors or Program Authority uses the results of both the contractor and the U.S. Government to evaluate the contractor's ability to consistently produce products meeting food safety requirements.
- f. Contractor's confidential methods and data. U.S. Government personnel will provide contractor QC or production data only to

concerned military inspection personnel, purchasing agencies, and/or civilian U.S. Government regulatory agencies. All personnel will limit access to U.S. Government/U.S. Federal/U.S. State examination and test data to concerned U.S. Government personnel. The Program Authority may provide test results to the contractor after consultation with the contracting officer.

- g. Use of the 3-out-of-5 concept.
- (1) The 3-out-of-5 concept provides a basis to determine the minimum acceptable contractor's performance based on verification sample results. Samples drawn as monitor samples at destination DO NOT apply to the 3-out-of-5 count.
- (2) Select the samples for initial verification at origin; the results from these samples are applicable to the 3-out-of-5 concept. Subsequent samples drawn at origin or destination are also verification samples and the results are applicable to the 3-out-of-5 concept.
- (3) Apply this procedure separately to each microbiological characteristic evaluated. For example, do not use a standard plate count (SPC) that exceeds the limit combined with a coliform count that exceeds the limit. This procedure is consistent with the PMO.
- (4) If the verification sample results exceed "M" quality specifications or wholesomeness tolerances, the proper authority will initiate suspension action. Do not apply the 3-out-of-5 procedure to adulterants or imminent health hazard situations, aseptically processed and packaged milk and milk products, surveillance programs for foodborne pathogens, toxicological contamination, or microbiological monitoring in retail/user operations.
- h. Monitoring toxic or noxious adulterants. The MACOM Veterinarian in consultation with Chief, USAVL, will design programs to monitor potentially toxic or noxious chemical adulterants (for example, pesticides, herbicides, antibiotics, additives, etc.), radiological contamination, and physical adulterants.

## **Chapter 3 Sanitation and Quality Assurance Visits**

#### 3-1. Sanitary inspections of establishments

Requirements for establishment sanitary inspections are in AR 40–657/NAVSUPINST 4355.4F/MCO P10110.31G. During initial sanitary inspections of establishments subject to the requirements of this regulation, the responsible inspector will select representative samples and submit them to the USAVL. These samples must conform to "m" values, and the inspector will evaluate the laboratory results prior to recommending sanitary approval.

#### 3-2. Quality assurance visits

- U.S. Army veterinary food inspection personnel in the rank of SSG or above will perform QAV on any food source establishment subject to the requirements of this regulation. MACOM Veterinarians will establish and publish procedures for an effective and efficient program.
- a. As a minimum, the inspector will review the following when conducting a QAV:
- (1) QC review. Review the establishment QC program, laboratory test procedures and results, corrective actions for previous test non-conformances and corrective actions from previous QAVs (if applicable).
- (2) Establishment sanitation. Evaluate the establishment's sanitation program to the extent possible by performing a walk-through inspection of the establishment. Do not confuse this inspection with a formal sanitary inspection that awards a sanitary compliance rating.
- (a) Although MACOM Veterinarians may order a full sanitary inspection, inspectors shall, as a minimum, review current inspection reports, equipment test reports, required certificates and seals, established pasteurization temperatures and holding periods, raw and finished/pasteurized product storage temperatures, production methods, product coding, and review the premises and select origin verification samples.

- (b) The inspector will notify the applicable inspection agencies of severe or potentially severe sanitary findings.
- (3) Exit briefing. Inspectors performing QAVs shall provide an exit briefing to establishment management personnel. The inspector will use this opportunity to discuss current trends, problem areas experienced by origin and destination inspectors, laboratory test results, and sanitary findings. The inspector will prepare a memorandum for record to document findings and discussions.
- b. Inspectors will perform QAVs to assist in resolving problems found by product testing. Do not perform QAVs on a routine schedule like formal sanitary inspections, but initiate them when product tests indicate potential or actual problems. When responsible personnel initiate more than two QAVs because of tests that indicate potential or actual problems, the responsible MACOM Veterinarian will decide whether inspectors will conduct a special sanitary inspection in accordance with AR 40–657/NAVSUPINST 4355.4F/MCO P10110.31G and whether inspectors will consult U.S. Federal or U.S. State or host nation officials.

## Chapter 4 Microbiological Safety and Quality Assurance Program

#### 4-1. Sampling schedules and sampling procedures

- a. Sampling schedules. The Program Authority will direct sampling at locations other than destination. The Program Authority will collect contracts and assign destination monitoring sites and origin inspection units.
  - b. Monitoring sites and inspection units.
- (1) In assigning sites and units, the Program Authority will consider—
- (a) Selecting a destination inspection unit in which a contract serves multiple locations.
  - (b) Selecting the closest qualified origin inspector.
- (2) Unless the MACOM Veterinarian makes an exception, all monitoring samples and all but the initial verification samples will be from the destination. When geographical areas inhibit proper sample submission, the origin inspector may request another inspector select and submit samples from an intermediate distribution point or destination. When destination sampling is not possible during suspension of deliveries, the origin inspector, with concurrence of the Program Authority, will specify option 1 or 2 origin sampling as described in paragraph 4–4.
- (3) Origin inspectors will select and submit origin samples after a contractor applies for reinstatement or after an identified imminent health hazard.
- c. Sampling frequency for laboratory testing. Base the sampling frequency upon the U.S. Government's microbiological and quality history for the contractor. Inspectors should be aware that a reduction in frequencies of military sampling is optional and will coordinate with the responsible Program Authority prior to making any changes. Sample definition and frequency are as follows:
  - (1) Verification samples are defined as-
- (a) One sample of each product that exceeded one or more tolerance values during the monitoring phase. Inspectors may select multiple production codes of a product for each sample submission. However, the inspector must maintain the appropriate warning period to the vendor. For example, if the inspector draws three consecutive code dates of 2% milk and determines that all were non–conforming, then he/she would assign only a warning status, not a suspension.
- (b) Five samples of the same type product for all RTE PHF that exceed "m" or "M" values(s) during the monitoring test phase.
- (2) Select verification samples weekly for new contractors; reinstated contractors; contractors inactive for more than 12 months; or whenever monitoring samples exceed "M," the criteria based on the appropriate product table in this chapter. Sampling will continue weekly until U.S. Government test results indicate there are no more than 1-out-of-4 test failures. The responsible Program Authority

will initiate suspension action as specified in paragraph 4–3f when microbiological limits exceed "M" values.

- (3) Monitoring samples are defined as-
- (a) One sample of each type product on each submission for fresh fluid and cultured dairy products and frozen desserts.
- (b) One sample of each type product for all RTE PHF during monitoring test phase.
- (4) Submit monitoring test samples from each product type a minimum of 4-out-of-6 consecutive months for microbiological characteristics in tables 4-1, 4-2, 4-3, and 4-4. When test results exceed "M" microbiological limits, the responsible Program Authority will—
- (a) Notify the contractor of verification start-up and explain the procedures associated with verification.
  - (b) Alert the origin inspector to initiate verification sampling.
- d. Suspension action. The responsible Program Authority may initiate suspension action as specified in paragraphs 4–3d, 4–3e and 4–3f.
  - e. Sample selection and handling procedures.
- (1) Focus sampling on container sizes that consumers purchase most frequently and on products or production/filler lines for which previous test results indicate problems.
- (2) Select samples in the presence of the contractor's representative (such as an establishment's management representative or delivery personnel when at the destination). The inspector will inform the representative the purpose for sampling and will not require the representative to certify that the selected sample represents the actual delivery quantity. However, the sample must represent a product that the contractor offers as meeting the requirements for the type of product to be supplied to the armed services.
- (3) Origin and destination sample selection, accountability, preparation and submission will be per specified requirements of any applicable specifications, technical data sheet (TDS), special instructions of TSGs of the military Services, and MACOM directives.
- (4) Select and handle the samples in a manner that will ensure no significant changes affect testing results from the time of collection until the start of testing by the laboratory. Aseptically remove samples from bulk containers using only certified sterile collection kits.
- (5) Safeguard samples to prevent the possibility of their being altered or violated.
- (6) Prepare DD Form 1222 (Request for and Results of Test) for each sample or group of samples submitted. Instructions for completing this form are in appendix C.
- f. Food types sampled. Sample the following food types (not necessarily all-inclusive) and test for microbiological quality, food pathogens, and noxious or toxic chemicals:
  - (1) RTE cooked meat and poultry products.
- (2) Fresh fluid dairy products to include, but not be limited to, fresh and cultured dairy products, frozen desserts, soft serve ice cream/milk and yogurt mix.
- (3) RTE salads and spread items (meat, seafood, and vegetable) with pH 4.6 or above. Such testing may be in conjunction with routine testing of salads as outlined in this chapter. Gelatins, fruit salads, and dessert items are exempt from sampling.
- (4) All RTE sandwich products except those that remain frozen from production until consumer sale and those with shellfire of less than 36 hours.
  - (5) Tofu.
  - (6) Soft cheese and cheese products (surveillance for pathogens).
- (7) Modified atmospheric packaged, smoked/cured seafood products. (NOTE: Establishments producing these items can provide to DOD activities only when specifically approved by the MACOM Veterinarian.)
  - (8) Other foods that the MACOM Veterinarian designates.

#### 4-2. Analytical requirements

Microbiological criteria for food safety and QA programs are specified in tables 4–1 through 4–4. Limits for potentially toxic substances are established by U.S. Federal regulatory agencies. These limits apply to samples selected at origin and destination. Use the

laboratory techniques and procedures as specified or referenced in the PMO and the current edition of "Standard Methods for the Examination of Dairy Products" as applicable. When these are not suitable or applicable for the product, use the techniques and procedures that are in substantial compliance with one of the following:

- a. Official Methods of Analysis of the Association of Official Analytical Chemists.
  - b. Bacteriological Analytical Manual, FDA.
- c. Current examination and test methods to detect adulterants, including pesticides, as recognized by the applicable Federal regulatory agency.
- d. Compendium of Methods for the Microbiological Examination of Foods, American Public Health Association.
- e. Current methods approved by the Advisor for Veterinary Laboratory Service to the Assistant Surgeon General for Veterinary Services.

#### 4-3. Nonconforming test results for quality programs

- a. Validity of results. Prior to reporting the failure, the Chief, USAVL will ensure that each test failure and conclusion are valid. If the Chief doubts the validity of a test failure, he/she will not use those results in the 3-out-of-5 procedure. The type of product will be re-sampled and the reason recorded on DD Form 2385. (See app C for instructions.)
- b. Valid individual test failures (1-out-of-4) (notice status). Upon notification of a monitoring sample failure, the Program Authority will direct the appropriate inspector to initiate verification sampling. For valid individual microbiological test failures during verification sampling, the Program Authority will immediately notify the producer. Only the producer, whether prime or subcontractor, need be notified. Testing frequency will remain weekly as specified in paragraph 4-1c(2). (See paragraph e below for suspension requirements as a result of an imminent health hazard.)
- c. Valid 2-out-of-4 test failures (warning status). For valid 2-out-of-4 microbiological test failures, the responsible Program Authority will—
- (1) Immediately warn the prime contractor and producer by telephone that the producer is in a warning status and complete DD Form 1232. Instructions for completing this form are in appendix C.
- (2) Immediately inform the appropriate contracting agency by telephone, facsimile, or electronic message. Provide copies of DD Form 1232 to the appropriate contracting agency with information copies to the prime contractor, subcontractor, destination inspector, and regulatory agencies as applicable. The report will state that the producer's microbiological and QC programs are unreliable for the type of product and characteristic concerned and that the producer must take corrective action.
- (3) Inform the inspector to take the next sample within 21 days of providing such notice, but not before the lapse of 3 days after notifying the contractor of the 2–out–of–4 warning status. Select samples as soon as possible. For infrequently produced items where production days may be weeks or months apart, sample the next production following notification of warning status.
- d. Valid 3-out-of-5 test failures (suspension status). For valid 3-out-of-5 microbiological test failures, the Program Authority will...
- (1) Take action to suspend procurement and delivery of that type of product. Note that food laboratory test results for frozen desserts, soft serve ice (cream) milk and yogurt, and salad–type convenience foods are not always "after consumption." Therefore, Government test results indicating nonconformance are cause for rejection of all future deliveries of a known nonconforming production lot.
- (2) Immediately notify, as appropriate, the contracting officer, prime contractor, subcontractor, destination inspector, and/or regulatory agencies by telephone, facsimile, or electronic message on the same day, and complete DD Form 1232. Address the form to the appropriate contracting agency with information copies to the prime contractor, subcontractor, destination inspector, and regulatory agencies as applicable. This report will state that the producer's microbiological and QC continues to be unreliable for the type of

product concerned and that the producer will not ship the product until the producer completes reinstatement procedures.

- e. Imminent health hazard.
- (1) A product or practice that creates or appears to create an imminent health hazard will be sufficient cause for the immediate suspension of delivery of all involved products until the problem is resolved. Examples include—
- (a) A critical establishment sanitary defect which could likely result in product contamination.
- (b) The laboratory confirmed presence of foodborne pathogens in a product for which zero tolerance has been established.
  - (c) A pasteurized product with a positive phosphates reaction.
- (d) A pesticide, antibiotic, mycotoxin, or other substance in quantities exceeding authorized limits.
- (e) An aseptically processed and packaged milk or milk product that does not meet commercial sterility requirements.
- (2) The testing laboratory will immediately report laboratory confirmed health hazard(s) to the origin inspector and the Program Authority by telephone, facsimile, or electronic message, confirmed by a follow-up copy of DD Form 1222.
  - (3) The Program Authority will-
- (a) Suspend procurement and delivery of that type of product. Note that test results for frozen desserts, soft serve ice cream/milk and yogurt, and salad-type convenience food are not always "after consumption." Therefore, U.S. Government test results indicating nonconformance are cause for rejection of future deliveries of a known nonconforming production lot.
- (b) Immediately notify, as appropriate, the contracting officer, prime contractor, subcontractor, origin/destination inspector, and/or regulatory agencies by the most expeditious method and complete a DD Form 1232. This report will state that the producer's QC continues to be unreliable for the type product concerned and the product is suspended until reinstatement procedures are completed.
- (c) Notify the appropriate U.S. State or local health agency with authority over the affected product. This action will be confirmed in writing to all personnel or agencies notified.
- (4) The Program Authority may reinstate products suspended from delivery due to an imminent health hazard only by following option 1 or 2, paragraph 4-4a or 4-4b, respectively.
- f. "M" values. Verification test results that exceed microbiological limits for "M" values for any type of product are sufficient cause for immediate suspension of delivery of all involved products. The Program Authority will—
- (1) Immediately suspend and report laboratory confirmed "M" value test results to the origin inspector by the most expeditious method confirmed by a follow-up DD Form 1222.
- (2) Notify by the most expeditious method the destination inspector(s), the appropriate contracting agency, and the prime contractor and subcontractor to prevent further deliveries of involved products.
- g. Quality history. Contractors who maintain a 0-out-of-4 or 1-out-of-4 test failure status have an acceptable quality history. Contractors who have a valid 2-out-of-4 or 3-out-of-5 test failure,

or who have had imminent health hazards, or who are in a reinstatement status have an unreliable quality history. Use the quality history to determine the frequency of QAVs as specified in paragraph 3–2b.

#### 4-4. Reinstatement procedures

The contracting agency will request the Program Authority to initiate reinstatement procedures. Because destination sampling is not possible during suspension of deliveries, the Program Authority will specify the use of one of the options in a and b below for reinstatement sampling.

- a. Option 1 concerns contractor sampling and approved laboratory testing.
- (1) The prime contractor will direct the producer to submit reinstatement samples to an approved laboratory. The contractor will submit to the USAVL a Certificate of Conformance signed by the prime contractor stating the corrective action taken and assuring compliance with contract requirements.
- (2) A numbered IMS List, U.S. Federal, or U.S. State-approved milk laboratory test result report will support this certification. This laboratory must be approved to perform the official test method specified in the contract, PMO, or specification, as applicable.
  - (3) The contractor will bear the cost of testing.
- (4) The samples submitted to the approved laboratory must be packaged end item samples identified as representing different lots produced after suspension.
- (5) Not more than 1-out-of-4 consecutive test results can show nonconforming results for the type of product and characteristic causing suspension. The Program Authority will make this determination on the results of not less than four consecutive valid test results of reinstatement samples.
- (6) If the type of product under suspension is a frozen dessert, the samples will include the same flavor(s) as the nonconforming flavor(s) causing the suspension.
- b. Option 2 concerns origin U.S. Government sampling and testing.
- (1) The U.S. Government will use verification sampling for the type of product suspended until U.S. Government test results show the contractor has acceptable microbiological and quality history (such as not more than 1-out-of-4 consecutive test results are nonconforming for the characteristic causing suspension).
- (2) The Program Authority will require 0-out-of-4 on suspensions due to imminent health hazards. The Program Authority will make this determination on the results of not less than four consecutive valid test results of reinstatement samples.
- c. When the Program Authority determines that the producer has regained acceptable QC based on option 1 or has met the requirements of option 2, he or she will notify the appropriate contracting agency. The contracting officer will then notify the contractor and origin inspector of the date to resume deliveries. Then, the origin inspector will notify the Program Authority of the date the contractor will resume deliveries and the status of the contractor's quality history.
- d. After reinstatement, the contractor has no quality history for the item or items reinstated. The Program Authority will initiate verification sampling to establish an acceptable QHR.

Table 4–1 Microbiological criteria for dairy products

wicrobiological criteria for dairy	products				
Product(s)	Standard Plate count (SPC) (See notes 3 & 4)	Coliform count (See note 4)	Combined yeast and mold count (See note 4)	Keeping Quality Test (See note 5)	Preliminary incubation count (See notes 4 & 6)
Floduct(s)	(See notes 3 & 4)	(See Hote 4)	(See Hote 4)	(See note 5)	(See flotes 4 & 6)
Aseptically processed and pack-	0 per ml	0 per ml	0 per ml		
aged milk and milk products	(See notes 7 & 8)	(See note 7)	(See note 7)		
Buttermilk and acidophilus milk		≤10 per gram			
Cottage cheese		≤10 per gram	≤10 per gram		
Cream, sour, cultured		≤10 per gram	≤10 per gram		
Grade A pasteurized milk and milk	≤20,000 per ml	≤10 per ml		≤100,000 per ml	≤200,000 per ml
products				(See note 9)	

Table 4–1
Microbiological criteria for dairy products—Continued

Product(s)	Standard Plate count (SPC) (See notes 3 & 4)	Coliform count (See note 4)	Combined yeast and mold count (See note 4)	Keeping Quality Test (See note 5)	Preliminary incubation count (See notes 4 & 6)
Ice cream products, flavored, fruit, and/or nuts	≤50,000 per gram	≤20 per gram			
Ice cream products, vanilla and plain flavored Ice milk, milkshake and/or frozen dessert mix:	≤50,000 per gram	≤10 per gram			
vanilla flavor other flavors Yogurt, chilled Yogurt, frozen, plain Yogurt, frozen, flavored Yogurt soft serve mix	≤50,000 per gram ≤50,000 per gram	≤10 per gram ≤20 per gram ≤10 per gram ≤10 per gram ≤20 per gram ≤10 per gram	≤10 per gram ≤10 per gram ≤10 per gram		

#### Notes:

Table 4–2 Microbiological limits for prepared salads and spreads

Counts	n	С	m	M
Aerobic plate count (APC)	5	2	100,000 per gram	1,000,000 per gram
E. coli most probable number (MPN)	5	2	<3 per gram	10 per gram
Yeast and mold count	5	2	200 per gram	1,000 per gram
Campylobacter jejuni <sup>1</sup>	5	2	100 per gram	1,000 per gram
Staphylococcus aureus 1	5	2	100 per gram	1,000 per gram
Clostridium perfringens 1	5	2	100 per gram	1,000 per gram
Bacillus cereus <sup>1</sup>	5	2	100 per gram	1,000 per gram
Salmonella species 1			Zero (0) tolerance <sup>2</sup>	, , ,
Listeria moncytogenes 1			Zero (0) tolerance 2	
E. coli 0157:H7 <sup>1</sup>			Zero (0) tolerance <sup>2</sup>	

Legend for Table 4-2:

n=number of samples examined.

c=maximum number of samples allowed with values equal to or above  $\ensuremath{\mathsf{m}}.$ 

m=values above this level, but below that of M are of marginal microbiological quality.

<sup>&</sup>lt;sup>1</sup> Phosphatase as specified in the PMO.

<sup>&</sup>lt;sup>2</sup> Products shall be free of antibiotic or pesticide residues or below the action levels established for such residues by the applicable Federal regulatory agency. Antibiotic residue testing shall be by the method described in the PMO. Examinations and test to detect adulterants, including pesticides, shall be conducted by methods recognized by the applicable Federal regulatory agency.

<sup>&</sup>lt;sup>3</sup> Not applicable to cultured products.

<sup>&</sup>lt;sup>4</sup> All counts are maximum allowed standards.

 $<sup>^5</sup>$  KQ Test: Products are held at  $7^{\circ}\text{C}~\pm1^{\circ}$  and tested (SPC  $32^{\circ}\text{C}$  for 48 hours) on manufacturers pull date.

<sup>&</sup>lt;sup>6</sup> Products are incubated (within 24 hours of packaging) at 21°C for 18 hours, a sample is plated on Standard Methods Agar, and plates are incubated at 21°C for 25–48 hours. Higher count allowed for older samples.

<sup>&</sup>lt;sup>7</sup> Nonconformances will be considered an imminent health hazard.

<sup>&</sup>lt;sup>8</sup> Either aerobic or anaerobic SPC.

<sup>&</sup>lt;sup>9</sup> This value (<100,000) is for a 10 day pull date product. The KQ limit can be adjusted to accommodate longer pull date products.

M=values above this level are unacceptable and the product is rejected and deliveries are suspended.

<sup>&</sup>lt;sup>1</sup> These tests/counts apply to products that have a ph >4.6.

<sup>&</sup>lt;sup>2</sup> No viable pathogen in a 25 gram sample.

Table 4–3
Microbiological limits for sandwiches and ready–to–eat meats

Counts	n	С	m	M
Aerobic plate count (APC)	5	2	100,000 per gram	1,000,000 per gram
E. coli (MPN)	5	2	<3 per gram	10 per gram
Campylobacter jejuni	5	2	100 per gram	1,000 per gram
Staphylococcus aureus	5	2	100 per gram	1,000 per gram
Clostridium perfringens	5	2	100 per gram	1,000 per gram
Salmonella species 1			Zero (0) tolerance <sup>2</sup>	, ,
Listeria moncytogenes 1			Zero (0) tolerance 2	
E. coli 0157:H7 <sup>1</sup>			Zero (0) tolerance 2	

Legend for Table 4-3:

n=number of samples examined.

c=maximum number of samples allowed with values equal to or above m.

m=values above this level, but below that of M are of marginal microbiological quality.

M=values above this level are unacceptable and the product is rejected and deliveries are suspended.

Table 4–4
Microbiological limits for tofu

wicrobiological lilling for told				
Counts	n	С	m	M
Aerobic plate count (APC)	5	2	1,000,000 per gram	1,000,000 per gram
E. coli (MPN)	5	2	100 per gram	2,000 per gram
Staphylococcus aureus 1	5	2	100 per gram	10,000 per gram
Salmonella species 1			Zero (0) tolerance <sup>2</sup>	
Listeria moncytogenes 1			Zero (0) tolerance 2	
Yersinia entercoliticus 1			Zero (0) tolerance 2	

Legend for Table 4-4:

n=number of samples examined.

c=maximum number of samples allowed with values equal to or above m.

m=values above this level, but below that of M are of marginal microbiological quality.

M=values above this level are unacceptable and the product is rejected and deliveries are suspended.

## Chapter 5 Microbiological Monitoring at Retail/User Level

#### 5–1. Purpose

This chapter describes guidelines for microbiological monitoring of ground meat processing, soft serve yogurt processing, and soft serve ice (cream) milk processing at the retail/user level. The applicable MACOM has the option to adopt, implement, and direct this program. The program will assist veterinary/medical food inspection personnel in monitoring microbial limits at various processing control points and identify unwholesome and inferior quality at the retail/user level. The guidelines in tables 5–1 and 5–2 will help veterinary/medical food inspection personnel interpret laboratory results and assist in follow—up testing.

#### 5-2. Responsibilities

- a. The commissary officer/accountable officer or designated representative is responsible for—
- (1) Ensuring the product(s) is (are) made available for testing.
- (2) Maintaining records as required by appropriate activity headquarters or applicable regulations.
- (3) Initiating corrective actions when notified by veterinary/medical food inspectors of nonconforming laboratory test results. When applicable, notify next higher organizational level (for example, Defense Commissary Agency (DeCA) regional office, or Army and Air Force Exchange Service (AAFES) staff veterinarian).
- b. Veterinary/medical personnel will perform responsibilities as outlined in paragraph 1–4 of this regulation.

#### 5-3. Sample selection and handling

a. General. The special instructions of TSGs of the military Services and/or MACOM directives will govern sample selection,

accountability, preparation, and submission. The samples must represent a product that the retailer/user is processing or packaging. Protect samples against any significant change that would affect test results during the interval between collection and laboratory analysis. Use aseptic sampling procedures at all times to eliminate any possibility of sample adulteration.

- b. Product samples. Samples should originate from intact retail containers or from aseptically collected non-intact samples. At a minimum, consider the following processing sites for sampling products:
- (1) *Beef trimmings*. Select samples from coarse ground and/or chopped trimming at the time of receipt; trimmings generated by the commissary; immediately prior to the first operational grind; and again prior to the second operational grind.
- (2) Finished ground beef, pork, and poultry. Select samples from the finished product at the end of packaging and the packaged product from display cases.
- (3) Soft serve products. Select samples from the raw mix at the time of receipt; the raw mix at the time immediately prior to processing in the soft serve machine; and the finished product exiting the soft serve machine.
- c. Environmental samples. Select environmental samples from food preparation equipment food contact surfaces (for example, grinders, knives, aprons, etc.). Consider bacterial counts valid only if they are obtained from food contact surfaces and processing equipment that have undergone routine cleaning/sanitizing procedures.

#### 5-4. Analytical requirements

The microbiological criteria for ground beef, ground pork, ground poultry, soft serve yogurt, and soft serve ice (cream) milk are in tables 5–1 and 5–2. Use these limits as an index to evaluate the

<sup>&</sup>lt;sup>1</sup> These tests/counts apply to products that have a ph >4.6.

<sup>&</sup>lt;sup>2</sup> No viable pathogen in a 25 gram sample.

<sup>&</sup>lt;sup>1</sup> These tests/counts apply to products that have a ph >4.6.

<sup>&</sup>lt;sup>2</sup> No viable pathogen in a 25 gram sample.

quality of raw material and processing equipment sanitation, facility sanitation, and food handlers' hygiene practices.

#### 5-5. Sample frequency

- a. Base the sample frequency on the microbiological and quality history for each product. Minimum sampling frequencies are as follows:
- (1) Monitoring samples. Submit monitoring samples whenever: the accountable officer receives a customer complaint; product shelf life is less than adequate; unsanitary environmental conditions exist; when, in the inspector's judgment, laboratory testing is necessary to protect the U.S. Government's interest or consumer's health; or when requested by the accountable officer/responsible officer. When

test results exceed microbiological limits in table 5–1 or 5–2, initiate verification sampling immediately.

- (2) *Verification samples*. Perform verification sampling on a minimum of five consecutive production days for each type of product. Samples will originate from processing points referenced in paragraph 5–3.
- b. If microbiological test results indicate that samples from all five consecutive days are within the established limits in tables 5–1 and 5–2, microbiological testing may be reduced. If the microbiological test results exceed the established limits, consider additional sampling and corrective action.

#### 5-6. Quality history records

MACOMs will establish requirements for microbiological monitoring QHRs. Records may be manual or automated. (See app C for guidelines on maintaining QHRs.)

Table 5-1				
Microbiological	criteria	at the	retail/user	level

Products	Aerobic Plate count (APC) (See note 2)	Fecal coliform count (See note 2)	Combined yeast and mold count (See note 2)	Coliform count (See note 2)
Ground beef, beef trimmings, pork and poultry; chilled or frozen	≤1,000,000 per gram	≤100 per gram		
Environmental swab or sponge samples (See note 3)	≤100 per 50 sq cm			≤10 per 50 sq cm
Yogurt, soft serve			≤100 per gram	≤100 per gram

#### Notes:

Table 5–2 Microbiological criteria for soft serve ice (cream) milk at the retail/user level

Counts	n	С	m	М
Standard plate count	5	2	≤50,000 per gram	≤250,000 per gram
Coliform MPN	5	2	≤100 per gram	≤1,000 per gram

#### Notes:

c=maximum number of samples allowed with values equal to or above m.

m=values above this level, but below that of M are of marginal microbiological quality.

M=values above this level are unacceptable. Cease production until correction is made and affected product disposed of properly.

<sup>&</sup>lt;sup>1</sup> Microbiological counts can be used as an index for evaluating the sanitation status of processing equipment and the facility.

<sup>&</sup>lt;sup>2</sup> All counts are maximum recommended limits.

<sup>&</sup>lt;sup>3</sup> Counts from unmeasured surfaces should be compared with previous counts from those surfaces.

<sup>&</sup>lt;sup>1</sup> n=number of samples examined.

## Appendix A References

#### Section I Required Publications

#### AR 40-657/NAVSUPINST 4355.4F/MCO P10110.31G

Veterinary/Medical Food Inspection and Laboratory Service. (Cited in paras 1-4h(1), 3-1, and 3-2b.)

#### **Bacteriological Analytical Manual**

(Cited in para 4–2*b*.) This manual is available from the Association of Official Analytical Chemists, 2200 Wilson Boulevard, Alexandria, VA 22201–3301.

## Compendium of Methods for the Microbiological Examination of Foods

(Cited in para 4–2*d*.) This manual is available from the American Public Health Association, 1015 Fifteenth Street, NW., Washington, DC 20005.

## Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement

(Cited in para 1-4g(2).) This document is available from Headquarters, U.S. Army Veterinary Command (Prov), ATTN: MCVS–FA, Fort Sam Houston, TX 78234–6000. Directories are also published by all MACOMs OCONUS.

#### Grade

(Cited in paras 1-4h(2), 1-4h(3), 1-5b, 2-2c, 2-2g(3), 4-2, 4-4a(2), and table 4-1.) Public Health Service/Food and Drug Administration Publication No. 229. This document is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

## Official Methods of Analysis of the Association of Official Analytical Chemists

(Cited in para 4–2*a*.) This book is available from Association of Official Analytical Chemists, 2200 Wilson Boulevard, Alexandria, VA 22201–3301.

## Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers (IMS List)

(Cited in paras 1–4*g*(2), 2–2*a* (2), 4–4*a*(2), and app B.) This document is available from the U.S. Food and Drug Administration, Milk Safety Branch, HFS–626, 200 C Street, SW., Washington, DC 20204.

#### Standard Methods for the Examination of Dairy Products

(Cited in para 4–2.) This book is available from American Public Health Association, 1015 Fifteenth Street, NW., Washington, DC 20005.

#### Section II Related Publications

A related publication is merely a source of additional information is merely a source of additional information. The user does not have to read it to understand this publication.

#### Assistant Secretary of Defense (Health Affairs)

Letter of Instruction Concerning Veterinary Services and the Safety and Wholesomeness of the Food Supply

## Dairy Establishments Surveyed and Approved for USDA Grading Service

This document is available from the U.S. Department of Agriculture, Agricultural Marketing Service, Dairy Division, Room 2750–South, P.O. Box 96456, Washington, DC 20090–6456.

## DLAR 4155.26/AR 40-660/NAVSUPINST 10110.8C/AFR 161-42/MCO 10110.38C

DOD Hazardous Food and Nonprescription Drug Recall System.

#### DODD 6015.5

Joint Use of Military Health and Medical Facilities and Services.

#### **DOD Federal Acquisition Regulation Supplement**

#### Federal Acquisition Regulation

## Food and Drug Administration Compliance Program Guidance Manual, Program 7303.037

#### MIL-STD 668

Sanitary Standards for Food Plants. Military standards are available from the Navy Aviation Supply Office, 700 Robbins Avenue, Philadelphia, PA 19111–5098.

#### MIL-STD 1155

Sanitary Standards for Frozen Dessert Plants.

#### MIL-STD 1162

Sanitary Standards for Cheese and Cheese Products Plants.

#### MIL-STD 1481

Sanitary Standards for Meat Processing Plants in Overseas Areas.

#### MIL-STD 1482

Sanitary Standards for Butter (and Related Products) Plants.

#### **USDA** Meat and Poultry Inspection Directory

This document is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

#### Section III

#### **Prescribed Forms**

#### **DD Form 2385**

Microbiological Quality History Record. (Prescribed in paras 2-2c, 4-3a, and app C.)

#### Section IV Referenced Forms

#### DA Form 11-2-R

Management Control Evaluation Certification Statement.

#### **DD Form 1222**

Request for and Results of Test.

#### **DD Form 1232**

Quality Assurance Representative's Correspondence.

## Appendix B Worldwide Veterinary Laboratory Services

Official laboratories furnishing laboratory services are as follows:

- a. Veterinary laboratory at BAMC and overseas Army medical facilities. (See table B-1.)
- b. USPHS laboratories and those State, county, city, and municipal laboratories approved by the USPHS for the wholesomeness testing of fresh dairy products. The current edition of the FDAs IMS List contains a list of approved laboratories.
- c. Other laboratories as individually authorized by TSG, DA, or MACOM Commanders.

#### Table B-1 Veterinary Service Laboratories

Laboratory

**DOD Veterinary Laboratory** Brooke Army Medical Center ATTN: HSHE-VS-L Building 2630 Fort Sam Houston, TX 78234-6200 Food Analysis Lab 1 Tripler Army Medical Center Schofield Barracks, HI 96857-5460 Chief, Veterinary Pub Hlth & Diag Lab Veterinary Services USAMEDDAC, Panama APO Miami 34004 U.S. Army Vet Lab-Europe 10th Medical Laboratory Building 3810 APO AE 09180-3619

#### Notes:

<sup>1</sup> The laboratory in Hawaii provides only chemical and microbiological testing of fresh dairy products and microbiological testing of commissary ground beef and convenience foods such as salads and prepared foods. BAMC tests other samples from Hawaii and the Pacific Rim.

#### Appendix C Quality History Records

#### C-1. Quality history records

Keep DD Form 2385 and quality history files for each type and line item provided by a manufacturer supplying fresh or cultured dairy products, frozen desserts, soft serve ice (cream) milk and yogurt, salad—type convenience foods, coarse ground and/or chopped meat products, or ground poultry products to the Government, or PHF tested under the food safety surveillance program. Suspense procedures will assure timely and orderly regulation of frequencies of sanitary inspections, QAV, and product sampling for testing. Place a copy of each DD Form 1222, DD Form 1232, DD Form 2385, and related correspondence in the quality history file. Keep the forms according to existing regulations, either in active or inactive status.

#### C-2. DD Form 1222

Send a DD Form 1222 (signed and with Section A completed) with each sample or group of samples submitted to the Government for testing. (See fig C-1 for an example of a completed DD Form 1222.) Accurately prepare forms with proper sample identification. The laboratory will complete section B of the DD Form 1222 and forward the original and one copy to the origin inspector and one copy to the destination inspector. (Exception: When sampling is at the origin, the original and two copies will be sent to the origin inspector.) On receipt of test results, the origin inspector will file the original in the contractor's (producer's) quality history file after annotating pertinent data on DD Form 2385. Additional copies may be used as enclosures to letters and reports as required. Use the instructions below to complete DD Form 1222, section A.

- a. Block 1. Enter the name and address of the laboratory to which the sample is submitted.
- b. Block 2. Enter the name and address of the inspection office submitting the sample(s), and indicate if it is at the origin or destination. Also enter the name and title of the individual submitting samples and the DSN or commercial telephone number with area code.
- c. Block 3. Enter the name and address of the prime contractor and all known contract numbers pertaining to the products being tested. Include Defense Logistics Agency, local, exchange, and/or other contract numbers as applicable.
- d. Block 4. Enter the name and address of the producing establishment. State "Same as Block 3" when this information is identical to information in Block 3.
- e. Block 5. Enter the description of the item to be tested or "See Block 16" (when submitting more than one type of sample).

- f. Block 6. Enter appropriate product sample number or "See Block 16" (when submitting more than one sample.)
- g. Block 7. Enter the "contractor's lot number" or "See Block 16" (when submitting more than one lot).
- h. Block 8. Enter the reason for submitting the sample, such as "GT" (Government testing), "RT" (reinstatement testing), "CT" (chemical testing), or "ST" (special testing).
- *i.* Block 9. Enter the time and date the sample was shipped to the laboratory.
- j. Block 10. Enter "End Item" for single sample submission or "See Block 16" when submitting more than one type of sample.
- k. Block 10a. Enter the quantity submitted or "See Block 16" when submitting more than one type of sample.
- *l. Block 11.* Enter "Unknown" unless the sample represents a known specific lot quantity. Use block 16 for additional data, as required.
  - m. Block 12. Enter the number and date of this regulation.
- n. Block 13. Enter the source of the sample(s), such as DeCA, AAFES, or contractor.
- o. Block 14. Enter the shipment method (such as United Parcel Service, Federal Express, Delta/American/United Express, U.S. Express Mail, U.S. Mail, or military courier).
- p. Block 15. Enter the time and date the samples were obtained. Enter the signature block of the veterinary/medical officer-in-charge (OIC). Ensure the OIC or noncommissioned officer in charge signs the block.
- q. Block 16. For all samples submitted, enter the sample number, product name and identity (type, grade, class), the product code date, date of pack (DOP) (pasteurization/processing/production date), and test desired. Enter the flavor when submitting frozen desserts. Enter "Pilot Included for Temperature" when submitting a chill product. A one-half pint container or equivalent is the minimum size for a pilot. A pilot is not required for frozen products. List no more than six samples on one DD Form 1222. Enter the security seal number when one is used for mail shipment.
- r. Block 17. Enter the inspection codes and the purchasing activity address that require copies of test results.

#### C-3. DD Form 1232

Use DD Form 1232 when referring nonconformance information to applicable Federal, State, or local agencies concerned with product requirements. (See fig C–2 for a completed sample of DD Form 1232.) Use the instructions below to complete DD Form 1232.

- a. Block 1. Enter the complete address of the appropriate contracting agency responsible for administration of the contract.
- b. Block 2. Enter the complete address of the originating office to include DSN or commercial telephone number.

- c. Block 3. List current contract(s), date(s) of expiration, and destination(s). Continue listing in the Subject block.
- d. Block 4. Enter the item description as listed on the contract to include the flavor as applicable.
  - e. Block 5. Enter the name and address of the prime contractor.
- f. Block 6. Enter the name and address of the manufacturer, if different from Block 5.
- g. Subject block. Enter information as applicable for 2-out-of-4 warning status, 3-out-of-5 suspension status, suspension status for imminent health hazards, or positive test results on verification samples for food pathogens and food surveillance programs. Additional information required in this block includes the following:
- (1) Enter the results of the last five test examinations being reported in descending order.
- (2) Enter any change of sampling frequency or contractor's status as applicable, for example, monitoring sampling increased to verification sampling, warning status (2–out–of–4 test failures), or suspension action (3–out–of–5 test failures).
- (3) Record notification information that supports notifying the contractor of status by telephone.
- (4) Record additional information or comments that will assist the reviewer in initiating corrective action.
- h. Block 7. Enter the signature block and signature of the QA representative (veterinary or medical inspection personnel).
  - i. Block 8. Enter applicable date.

#### C-4. DD Form 2385

Maintain a DD Form 2385 for each product type supplied by the manufacturer. Reproduce the DD Form 2385 locally on 8 1/2– by 11–inch paper; a copy of this form is located at the back of this regulation for reproduction purposes. Enter only validated test results on the DD Form 2385. When it is determined that test results are invalid or that sampling occurred prior to 3 days after notifying the contractor of 2–out–of–4 test failures, line out non–conforming test results and annotate a statement in block 13. Circle valid non-conforming test results. Circling these results depicts the 3–out–of–5 concept. Circling also indicates that an additional action is required. (Note: The 3–out–of–5 concept does not apply to the food pathogen

surveillance program.) Record all reinstatement test results, including results of testing by option 2. (See para 4–4*b*.) Use the instructions below to complete DD Form 2385.

- a. Block 1. Enter the activity responsible for maintaining the DD Form 2385.
- b. Block 2. Enter the complete product description, as listed on the contract.
  - c. Block 3. Enter the name and address of the prime contractor.
- d. Block 4. Enter the name and address of the manufacturer, if different from block 3.
- e. Blocks 5a and b. Enter the name and telephone numbers for the prime contractor or manufacturer's representative to whom non-conformances are to be reported.
- f. Block 6. Record the contractual document(s) that cite the actual requirements for characteristics recorded in block 9, (for example, specifications, TDS, or master solicitation number).
  - g. Block 7. Enter the test(s) being logged on the QHR.
- h. Block 8a. Enter the date and time the sample was taken from the establishment.
- i. Block 8b. Enter the date and time the results were received from the USAVL.
  - j. Block 9. Enter the product code.
- k. Block 10. Check the block (a, b, or c) that indicates the type sample being tested.
- 1. Block 11. Entries in blocks 11a through 11e will reflect actual inspection results.
- m. Block 12. Enter the name of the pathogen identified, when applicable.
- n. Block 13. Enter action taken based on inspection results. As a minimum, enter "no action required."

#### C-5. File maintenance

Maintain files according to existing regulations. In addition to the forms listed in paragraph C-1, files should contain copies of—

- a. All correspondence.
- b. Memoranda for record.
- c. Results of inspections.
- d. Reports of nonconformances.
- e. Any special instructions affecting the administration of the contract.

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See Block 16		Block 16	Block 16			2 Feb 92
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Figure C-1. Example of a completed DD Form 1222

#### QUALITY ASSURANCE REPRESENTATIVE'S CORRESPONDENCE ı. TO: 2. FROM: (Name, address, ZIP Code, and office telephone Cdr. Defense Personnel Support Center Chief, U.S. Army Veterinary Laboratory ATTN: DPSC-HOPA Brooke Army Medical Center 2800 South 20th Street Bldg. 2630 Philadelphia, PA 19101 Fort Sam Houston, TX 78234-6200 3. CONTRACT, P. O., OR O. I. NUMBER 4. ITEM See Below Milk, Whole, Fresh, Type I, Class 1 5. PRIME CONTRACTOR NAME, ADDRESS AND ZIP CODE S. PLANT NAME, ADDRESS AND ZIP CODE Dairy Pride Co. Virginia Valley Dairy 915 18th Street NW 1822 Braddock Road Richmond, VA 23219 Springfield, VA 22030 SUBJECT: 2-out-of-4 test failures "Warning Status" This correspondence is in support of the telephone conversation between Mr. Mike Mingel and SSG Moe on 22 Jan 92/0830 hrs. Virginia Valley Dairy has been placed in a "Warning Status" for Standard Plate Counts (SPC) for the item in block 4. Weekly microbiological testing for SPC will continue until test results show there are no more than 1-out-of-4 test failures for SPC. If 3-out-of-5 test failures occurs for SPC the affected product will be recommended for suspension. The producer's microbiological and quality program is unreliable for the referenced product for SPC levels and corrective action is required. The following test results are provided: Date Product Sampled' Code SPC Coli Phos Action Taken 14 Jan 92 23 Jan 70,000 6 Neg <del>20</del>,000 Warning Status - SPC 15,000 9 Jan 92 18 Jan 4 18,000 Neg NA 30 Dec 91 8 Jan 25,000 8 Neg 19,000 Notice Status - SPC 23 Dec 91 1 Jan 17,000 25 Neg 60,000 Notice Status - Coli. Increased to Weekly Testing 15 Nov 91 24 Sep 18,500 8 Neg 60,000 NA The plant is providing products for Dairy Pride Company under the following contracts: DLA13H-9X-M126 EXP 12/92 Ft. Lostin D. Woods DLA13H-9X-D186 EXP 12/92 Ft. Spiny, Ft. Poll, Ft. Sandflea DLA13H-9X-D192 EXP 12/92 Ft. Blank DLA13H-9X-D250 EXP 6/93 Camp Swampy SAMPLE

DD FORM 1232 EDITION OF 1 OCT

Dairy Pride Co. VA Valley Dairy

Cdr, NE VSSA ATTN: N Va Dist

EDITION OF 1 OCT 68 MAY BE USED UNTIL EXHAUSTED

. DATE

22 Jan 92

+ USGPO 1986 -491-003/50430

Figure C-2. Example of a completed DD Form 1232

## Appendix D Management Control Evaluation Checklist

#### D-1. Function

The function covered by this checklist is to ensure internal management control measures are in place that evaluate the Food Safety and Quality Assurance Program.

#### D-2. Purpose

The purpose of this checklist is to assist the MACOM Veterinarians; Chiefs, USAVL; and U.S. Army Veterinary Food Inspectors in evaluating the key management controls listed below. It is not intended to cover all controls.

#### D-3. Instructions

Base answers on the actual testing of key management controls (for example, document analysis, direct observation, sampling simulation, other). Explain answers that indicate deficiencies and indicate corrective action in supporting documentation. Evaluate these management controls at least once every 5 years. Document certification on DA Form 11–2–R (Management Control Evaluation Certification Statement).

#### D-4. Test questions

- a. Are food products checked to assure purchase only from approved sources? (para 1-4)
- b. Are vehicles inspected for sanitation at the time of product delivery to military installations? (para 1-4)
- c. Are products inspected for temperature requirement compliance at the time of delivery? (para 1-4)
- d. Are inspection documents properly prepared, logged in, and when required, submitted to the proper authority? (para 1-4)
- e. Are commercial packaging, packing, labeling and/or marking inspected for compliance with purchase documents? (para 1-4)
- f. Are QHRs for each contractor maintained by the responsible veterinary/medical personnel? (1–4)
- g. Are required tests, sampling frequencies, and examinations for wholesomeness standards accomplished as prescribed? (paras 2–2 and 4–1)
- h. Are test results used to evaluate the contractor's ability to consistently produce wholesome products? (para 2–2)
- *i.* Is the 3-out-of-5 concept used to determine minimum acceptable contractor performance? (para 2-2)
- *j.* Are representative samples of PHF properly documented on DD Form 1222 and sent to the appropriate USAVL? (para 3–1 and app C)
- k. Do results conform to the "m" value prior to the establishment receiving initial sanitary approval? (para 3-1)
- Is the contractor's QC program reviewed during a QAV? (para 3-2)
  - m. Are QAVs conducted as required? (para 3-2)
  - n. Are results of QAVs recorded? (para 3-2)
- o. Are inspectors noting whether deficiencies noted in prior reports are corrected? (para 3-2)
- p. Are sampling schedules and procedures conducted as prescribed? (para 4-1)
- q. Are samples selected from the most frequently purchased product line and from applicable production lines? (para 4–1)
- r. Are specified techniques and procedures used to determine microbiological criteria? (para 4-2)
- s. Are supervisory personnel (Veterinary Unit Commanders or Chief, USAVL) performing reviews to ensure proper procedures are followed for nonconforming test results? (para 4–3)
- t. Are the prescribed reinstatement procedures followed? (para 4-4)
- u. Are specified PHF tested in accordance with microbiological criteria as prescribed? (tables 4-1 to 4-4)
- v. Does the commissary officer/accountable officer ensure products are available for testing? (para 5-2)

- w. Are veterinary/medical personnel performing their responsibilities in monitoring microbial limits at the retail/user level? (para 5–2)
- x. Do samples selected represent products that are being processed for consumption at the user level? (para 5–3)
- y. Do sample procedures eliminate possibilities of sample adulteration? (para 5-3)
- z. Are prescribed microbiological criteria being used and enforced? (para 5-4)
- aa. Is the sampling frequency based upon the quality history for each product? (para 5-5)
  - bb. Is the QHR properly maintained and used correctly? (app C)

#### D-5. Supersession

This checklist replaces the checklists for Health Care/Veterinary Wholesomeness Assurance Program for Fresh and Cultured Dairy Products and Frozen Desserts and Destination Inspection of Salad–Type Convenience Food previously published in DA Circular 11–93–1.

#### D-6. Comments

Help make this a better tool for evaluating management controls. Submit comments to Headquarters, Department of the Army, Office of The Surgeon General, Assistant Surgeon General for Veterinary Services, ATTN: DASG-VCP, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

Glossary

Section I **Abbreviations** 

**AAFES** 

Army and Air Force Exchange Service

AO

area of operation

aerobic plate count

**BAMC** 

Brooke Army Medical Center

Coli Coliform

CFR

Code of Federal Regulations

CONUS

continental United States

CT

chemical testing

Department of the Army

**DeCA** 

Defense Commissary Agency

Defense Logistics Agency Regulation

DOD

Department of Defense

DODVL

Department of Defense Veterinary Laboratory

DOP

date of pack

Federal Acquisition Regulation

**FDA** 

Food and Drug Administration

Government testing

Interstate Milk Shippers

Keeping Quality

MACOM

major Army command

Marine Corps Order

**MEDDAC** 

medical department activity

MIL-STD

military standard

MKO

Mosley Keeping Quality

milliliter

**MPN** 

most probable number

**NAVSUPINST** 

Navy Supply System Command Instruction

officer in charge

potentially hazardous food

Preliminary Incubation

Pasteurized Milk Ordinance

**OA** 

quality assurance

OAV

quality assurance visit

OC

quality control

OHR

quality history record

reinstatement testing

RTE

ready-to-eat

standard plate count

ST

special testing

technical data sheet

TSG

The Surgeon General

**USAVL** 

U.S. Army Veterinary Laboratory (CONUS or OCONUS)

United States Code

U.S. Department of Agriculture

**USDC** 

U.S. Department of Commerce

**USPHS** 

U.S. Public Health Service

Section II **Terms** 

Aerobic plate count

Method for measuring bacterial populations in a food product expressed as a colony count per unit or colony forming units per unit.

Adulterated

Any product covered by this regulation if one or more of the conditions exist as described in 21 CFR 402 as amended. For the purpose of this regulation, an adulterated product is unwholesome.

Approved laboratory

Any military, numbered IMS List, U.S. Federal, or State testing facility certified by the MACOM Commander to test food products.

Characteristic

Any requirement specified or referenced in this regulation that may be evaluated by test or examination.

Coliform bacteria

Short rod shaped bacteria that consist of all aerobic and facultative anaerobic, gram negative, non-sporeforming bacteria that ferment lactose with gas formation. The intestinal tract of an animal is a major source of these bacteria.

Directory

The Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement including annexes, published by U.S. Army Veterinary Command (Prov) or other OCONUS MACOMs.

**Destination** inspector

The military food inspection activity responsible for performing inspection of foods at the point of acceptance by the Government.

Escherichia coli

Gram negative bacteria that are part of the normal flora of the intestinal tracts of man and animals.

Establishment

A place of business or residence with its furnishings and staff that produces subsistence or wishes to produce subsistence for the U.S. military.

Examination for microbiological and quality characteristics

Laboratory testing and physical determination including temperature and age of the product, sensory examination, and integrity and cleanliness of containers.

Food contact surfaces

Those surfaces of equipment and utensils with which food normally comes in contact; and those surfaces from which food may drain, drip, or splash back into food or onto surfaces normally in contact with food.

#### Fresh and cultured dairy products

Milk and milk products as defined in the USPHS Grade A Pasteurized Milk Ordinance No. 229, as amended.

#### Frozen desserts

Products that include ice cream, mellorine, sherbet, ice milk, water ice, ice cream mix, ice milk mix, milk shake mix, and other similar frozen desserts, including frozen novelties.

#### Imminent health hazard

A product or practice that creates or appears to create a significant threat of danger to health that must be corrected immediately.

#### Intact sample

A sample of an unopened consumer-ready packaged product.

#### **Interstate Milk Shippers List**

The listing of "Sanitary Compliance and Enforcement Ratings of Interstate Milk Shippers" published by the U.S. Food and Drug Administration.

#### Like product

A particular item prepared from the same species of raw material and having the same product name regardless of brand name or package size.

#### Listeria monocytogenes

Small rod shaped, motile, gram positive, non-sporeforming bacteria. These bacteria are found in soil, water, vegetation, and in the intestines of mammals, birds, and some fish.

#### "M" value

Exceeding microbiological counts that are the limits of wholesomeness or where microbiological values used to determine quality exceed the limits of wholesomeness (for example, a prepared salad with an APC of >1,000,000 per gram).

#### Mellorine

A frozen, pasteurized product, which, except for the fat content, is similar in composition to ice cream or milk. The fat used is a mixture of vegetable fats. "Imitation ice cream" is an equivalent term.

## Microbiological and quality assurance procedures

Procedures used by military inspectors to assure wholesomeness of products supplied to the Armed Forces, to include product examination and test, establishment sanitary inspections, and quality assurance visits, as appropriate.

#### Monitoring program

A program designed to regulate the vendor's compliance with accepted microbiological and chemical standards.

#### Most probable number

Technique used in the determination of the number of bacteria in a food product. The MPN method is based on subdividing the sample and therefore may be described as a multiple tube dilution to extinction method.

#### Origin inspector

The U.S. Army veterinary food inspection activity having responsibility for the geographical area in which the contractor's production facility is located.

#### Potentially hazardous food

Any food or food ingredient, natural or synthetic, in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms, or the slower growth of *C. botulinum*. (See TB MED 530 for a detailed definition.)

#### **Program Authority**

The individual designated by the MACOM Veterinarian to administer the Veterinary/ Medical Laboratory Food Safety and Quality Assurance Program.

#### Sanitarily approved food establishments

Food establishments approved for Armed Forces procurement as prescribed by AR 40–657/NAVSUPINST 4355.4F/MCO P10110.31G. "Approved source" is an equivalent term.

#### Standard plate count

Method for measuring viable bacterial populations in most food products. It is the method specified in the PMO to examine raw and pasteurized milk and milk products.

#### Test for microbiological characteristics

Refers to standard plate count, coliform count, combined yeast and mold count, phosphates, Keeping Quality or Preliminary Incubation count, aerobic plate count, and *Escherichia coli* count. Also includes food pathogens for the purpose of surveillance programs of potentially hazardous foods.

#### Verification samples

Five samples of the same type product collected after an intact sample tests positive under the monitoring program.

## Veterinary or medical food inspection personnel

A term that refers to the U.S. Army Veterinary Services personnel.

#### Wholesomeness

In sound condition, clean, free from adulteration, and otherwise suitable and safe for human consumption.

#### Section III

#### Special Abbreviations and Terms

This section contains no entries.

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For use of this form, see AR 11-2;	the proponent agency is ASA(FM).	
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documentation will be retained on file subject	to audit/inspection until superseded by a subs	equent management control evaluation.
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THE THE HOUSE AND HILL		b. DATE CERTIFIED
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DA FORM 11-2-R, JUL 94

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